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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|-----------------|----------------------|---------------------|------------------|--|
| 10/659,948 | 09/10/2003 | Timothy A. Hovanec | P 0294309 081289 | 7889 | |
| Pillsbury Winth | 7590 12/03/2007 | | EXAM | INER | |
| Intellectual Property Group Suite 2800 725 So. Figueroa Street Los Angeles, CA 90017-5406 | | | MARX, | MARX, IRENE | |
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| | | | 1651 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | |
|--|---|---------------------|--|--|--|
| | 10/659,948 | HOVANEC, TIMOTHY A. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Irene Marx | 1651 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| Responsive to communication(s) filed on <u>13 September 2007</u>. This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4) Claim(s) 1-4,6,7,16,18,20 and 21 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-4, 6-7, 16, 18 and 20-21 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | • | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other: | ate | | | |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/13/07 has been entered.

Claims 1-4, 6-7, 16, 18 and 20-21 are being considered on the merits.

Claims 1-4, 6-7, 16, 18 and 20-21 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims 1, 16, 18, and 20 are missing the critical step of culturing or growing the bacterial cells in order to oxidize ammonia to nitrite in the process as claimed. It is submitted that merely providing for "providing" cells fails to achieve the preamble of "alleviating or preventing the accumulation of ammonia", unless the aquarium is merely filled with water.

In addition, the as-filed specification fails to define what constitutes "an amount sufficient to alleviate or prevent the accumulation of ammonia in the aquarium" to be introduced into any size aquarium for a bacterial strain have the required identity to or a strain comprising SEQ ID NO: 1.

The as-filed specification states, for example:

[0017] The present invention also includes methods of alleviating the accumulation of ammonia in a medium. The methods include a step of placing into the medium a sufficient amount of a bacterial strain or strains or a composition comprising a bacterial strain or strains, wherein the 16S rDNA of the bacterial strain or strains has the nucleotide sequence(s) of SEQ ID NO:1,

[0047] The amount of the bacterial strain(s) is sufficient if the added bacteria can alleviate or prevent the accumulation of ammonia in the medium. In general, the addition

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of one or more of the bacterial strains of the invention to a freshwater or saltwater aquarium is expected to reduce the maximum ammonia concentration by at least 50% over the level which would be attained in the absence of the bacterial strain(s).

This is not informative as to how to proceed, particularly since the issue of "prevention" is not addressed, and no amounts disclosed or even suggested bacterial strain have the required identity to or a strain comprising SEQ ID NO: 1.

In addition, the written disclosure states:

[0098] Therefore, these two newly discovered bacteria Type A AOB (SEQ ID NO:1) and Type A1 (SEQ ID NO:2) predominate in low ammonia concentration environments, such as aquaria; and, when added to such an environment in a more purified state than they naturally occur, can accelerate the establishment of ammonia oxidation in such an environment (discussed below).

[0102] While Type A AOBs are the most important member of a successful AOB nitrifying community for low ammonia environments such as aquarium, they are not the only AOB present. Other AOB, such as Type B (SEQ ID NO:3), may be necessary for the system to efficiently cope with fluctuating concentrations of ammonia even over short (days) periods of time.

Thus, it cannot readily be assessed whether the addition to any size aquarium whether populated or overpopulated by fish of some unidentified amount of bacteria that comprise a nucleotide sequence that has at least 96% identity over the full length thereof to SEQ ID NO: 1 or that comprise the 16S rDNA nucleotide sequence set forth in SEQ ID NO: 1 will, in fact, prevent or alleviate the accumulation of ammonia in the aquarium. The prevention aspect is not addressed with any particularity.

Response to Arguments

Applicant's arguments and Grossheider Declaration have been fully considered but they are not deemed to be persuasive.

The data in the Declaration pertain to "Biospira". The correlation between the graphs presented and the instant invention cannot be readily assessed.

There is no clear indication as to

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1) of the identity of the bacterial cells used, i.e., to what extent "Biospira" comprise a bacterial strain comprising a nucleotide sequence that has at least 96% identity over the full length thereof to SEQ ID NO: 1, or comprising the 16S rDNA nucleotide sequence set forth in SEQ ID NO: 1, and

2) the amount of bacterial cells comprising a nucleotide sequence that has at least 96% identity over the full length thereof to SEQ ID NO: 1, or that comprise the 16S rDNA nucleotide sequence set forth in SEQ ID NO: 1 provided that constitute an amount sufficient to alleviate or prevent the accumulation of ammonia in the aquarium.

Applicant asserts that the test evaluates how NH₄Cl is transformed into nitrite and later from nitrite into nitrate. The data, if any, on the first graph presented cannot be readily interpreted (NO₂-N mg/l). Applicant also asserts that the results demonstrate immediate nitrification upon introduction of the "claimed bacterial strain". Yet the correlation between "BioSpira" and the bacterial strain as claim designated is not identified with any particularity. The type and nature of aquarium used in the test and as claimed is similarly not clearly delineated. It appears that flasks filled with water containing a certain amount of ammonia were used. However, this does not address the "prevention" aspect with any particularity or how to determine the amount required alleviation or prevention of accumulation of ammonia in any size aquarium for a bacterial strain comprising a nucleotide sequence that has at least 96% identity over the full length thereof to SEQ ID NO: 1, or comprising the 16S rDNA nucleotide sequence set forth in SEQ ID NO: 1 in the claimed context

Therefore, the significance of the results is not readily apparent.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866, 217-9197 (toll-free).

> Irene Marx **Primary Examiner**

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